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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,573	11/21/2003	Jen-Leih Wu	33151-188802	3665

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EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,573	WU ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to an isolated polynucleotide comprising a liver-specific expression control sequence that modulates L-FABP, classified in class 536, subclass 23.1.

II. Claim 15, drawn to a method for detecting L-FABP promoter activity using a cell comprising a polynucleotide comprising a liver-specific expression control sequence that modulates L-FABP operably linked to a reporter sequence, classified in class 435, subclass 6.

III. Claims 16-20, drawn to a transgenic fish who genome comprises a polynucleotide comprising a liver-specific expression control sequence that modulates L-FABP operably linked to a reporter sequence, classified in class 800, subclass 20.

IV. Claims 21 and 22, drawn to a method of using a transgenic fish whose genome comprises a polynucleotide comprising a liver-specific expression control sequence that modulates L-FABP operably linked to a reporter sequence to screen for agents that affect liver growth, classified in class 800, subclass 3.

V. Claims 23 and 24, drawn to a method of using a transgenic fish whose genome comprises a polynucleotide comprising a liver-specific expression control sequence that modulates L-FABP operably linked to a reporter sequence to screen genes affecting liver development by injecting the fish with an inhibitor of said gene , classified in class 800, subclass 3.

VI. Claims 25-29, drawn to a method of using a transgenic fish whose genome comprises a polynucleotide comprising a liver-specific expression control sequence that modulates L-FABP operably linked to a reporter sequence to screen for mutants that generate liver disease, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct. Invention I is drawn to an isolated nucleic acid and Invention II is drawn to a method of using a cell. The isolated nucleic acid can be used as a probe while the cells are used in a method of detecting gene activity. The method of using the cells is not required for the nucleic acid. The nucleic acid and the method of using the cells are classified differently. It would require an undue burden to search Inventions I and II together.

Inventions I and III are patentably distinct. The inventions are drawn to different products with different structure, function and use that require different technical considerations. Invention I is drawn to an isolated nucleic acid that can be used as a probe or to express protein in cells. Invention III is drawn to a transgenic fish that can be used to screen for mutations affecting liver development. The inventions are classified differently. It would require an undue burden to search Inventions I and III together.

Invention I and each of Inventions IV-VI are patentably distinct. Invention I is drawn to an isolated nucleic acid and Inventions IV-VI are drawn to methods of using a transgenic fish. The transgenic fish is not necessary for the nucleic acid and the nucleic acid has uses other than in making the fish used in Inventions IV-VI. For example, the nucleic acid can be used as a probe. The inventions are classified differently. It would require an undue burden to search Invention I and any of Inventions IV-VI together.

Inventions II and III are patentably distinct. The inventions are drawn to different products with different structure, function and use that require different technical considerations. Invention II is drawn to a method of using a cell in vitro to detect promoter activity. Invention III is drawn to a transgenic fish that can be used to screen for mutations affecting liver development. The inventions are classified differently. It would require an undue burden to search Inventions II and III together.

Invention II and each of Inventions IV-VI are patentably distinct. Invention II is drawn to amethod of using a cell in vitro and Inventions IV-VI are drawn to methods of using a transgenic fish. The methods of using the transgenic fish is not necessary for the method of using the cells. The methods require different method steps and different technical considerations. The inventions are classified differently. It would require an undue burden to search Invention II and any of Inventions IV-VI together.

Inventions IV-VI are patentably distinct. Invention IV is drawn to a method of screening for agents that affect liver growth. Invention V is drawn to identifying genes that affect liver development by injecting inhibitors of a known gene. Invention VI is drawn to screen for mutations that affect liver disease. The methods require different method steps and different technical considerations. It would require an undue burden to search any of Inventions IV-VI together.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632